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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,929	01/08/2004	Knut-Egil Loekling	PN0301	5513

7590 06/22/2007

Amersham Health, Inc.
IP Department
101 Carnegie Center
Princeton, NJ 08540

EXAMINER	
BARHAM, BETHANY P	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
06/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,929	LOEKLING ET AL.	
	Examiner	Art Unit	
	Bethany P. Barham	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 08/09/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of IDS filed on 08/09/2007 is acknowledged. Claims 1-19 are pending. Claims 1-19 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 10 recites the broad recitation "free radicals, compounds comprising transition metals and compounds

comprising lanthanide metals," and the claim also recites "preferably transition metal chelates, transition metal salts, and lanthanide metal chelates" and "more preferably Gd-chelates, etc..." which is the narrower statement of the range/limitation.

Claims 14 and 18 provide for the use of the composition for the manufacture of a contrast agent (claim 14) or medicament (claim 18), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14 and 18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,096,720 ('720) Love et al.

The limitations of the claims 1-6 are taught:

- '720 teaches sterically stabilized liposomes comprising a phospholipid having an amino head group such as phosphatidylethanolamine, such as dimyristoyl phosphatidylethanolamine, distearoyl phosphatidylethanolamine, etc., which can be derivatised with polyethylene glycol and an acylglycerol lipid having at least 12 carbon atoms such as myristoyl, palmitoyl, etc groups and one acyl group such as 1,2-dipalmitoyl-sn-3-succinyl glycerol (claims 1, 17-22, 30-32, 34, and 37-39 and col. 7, line 37-col. 8, line 62).
- The polyethylene glycol derivatised phosphatidylethanolamine comprises 1-20% mole of the total lipid content (claim 23).

The limitations of claims are 15-18 taught:

- A method of treating mammalian cancer and/or inhibiting expression in tissues or cells which comprises administering a composition according to claim 1 (a drug containing liposome) to a mammal in need of such a treatment (claims 1 and 43-44). The invention of '720 teaches oligonucleotide-containing liposomes prepared using known methods of preparation of drug-containing liposomes, and treatment of diseases such as mammalian cancer, particularly human cancer such as lung, stomach, renal, breast, laryngeal, pancreatic, colorectal cancers and malignant melanoma (col. 9, lines 16-60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 7-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,096,720 ('720) Love et al in view of US 6,159,445 ('445) Klaveness et al. The limitations of claims 1 and 7-12 are taught:

- '720 is taught above and teaches liposomes comprising phosphatidylethanolamine and an acylglycerol lipid having at least 12 carbon atoms such as myristoyl, palmitoyl, etc groups and one acyl group, such as 1,2-dipalmitoyl-sn-2-succinyl glycerol.
- '720 does not teach imaging or contrast agents.
- '445 teaches that is it known in that art that contrast agents are used for imaging enhancement in X-ray, MRI, ultrasound, and nuclear medicine and are in a carrier matrix or encapsulated in liposomes (col. 1, line 17-col. 2, line 2). '445 teaches that fluid containing liposomes cause contrast enhancement in light imaging methods and are useful in in vivo diagnostic light imaging (col. 7, line 56-col. 8, line 18). The invention of '445 comprises a medium for imaging modalities comprising liposomes which are known to be suitable for MRI, X-ray, ultrasound imaging containing contrast agents such as paramagnetic ions, metal chelates,

paramagnetic and/or superparamagnetic agents, iron chelates, iodine, etc (col. 13, line 20-col. 14, line 25). '445 teaches that the liposomes can carry photolabelled particles (col. 10, lines 55-58).

The limitations of claims 13-19 are taught:

- In vivo studies are shown in Example 25 of iodixanol containing liposomes and results in enhancement of scattering in the tumor. '445 teaches that liposomes are known to deliver imaging agents to tumors and that imaging modalities containing liposomes are also suitable for controlled extended release of active compounds (col. 13, lines 55-65 and col. 14, lines 1-7).
- '445 teaches administration to human or animal of the above imaging particles may be formulated in a liposome for the in vivo light imaging of tumors, organs, ducts, etc (claims, 1 and 14 and col. 18, lines 27-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of '720 and '445. One of ordinary skill in the art would have been motivated to combine since both teach liposomes and therapeutic agents. '720 teaches the specific liposome that is claimed by applicant for therapeutic use in tumors, while '445 teaches that several contrast agents are known for use in treating and imaging tumors (nuclear medicine and MRI, ultrasound, etc). As such one of ordinary skill in the art seeking to treat a mammalian subject with a pH sensitive therapeutic liposome of '720 would know how to image and treat the tumor using liposomes by looking to '445.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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